Pfizer Australia Pty Ltd

Submission into the Review of the Medicines Australia Code of Conduct 17th Edition

This submission is not confidential.
Medicines Australia may quote from this submission in any reports prepared about the review of the Code of Conduct and may publish this submission on the Medicines Australia website.

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Pfizer proposals for changes to Medicines Australia Code of Conduct 17th Edition - Transparency

Executive Summary

Pfizer Australia strongly supports increased transparency in our industry. We believe it is important that we work with healthcare professionals to provide them with information about the safe, effective and appropriate use of our medicines. At the same time we acknowledge the community's desire to have confidence in the relationships between pharmaceutical companies and doctors. For Pfizer, the transparent reporting of our interactions with healthcare professionals is one way we achieve this, along with adherence to our own strict policies and procedures. This commitment to transparency is reflected in the content of this submission to the review of the MA Code of Conduct.

The primary purpose of an educational meeting must always be to enhance medical knowledge, and sponsorship must never carry any obligation for the doctor to prescribe a particular medicine. This interaction is an important part of the health system that ensures health professionals have the latest information, patients get the medicines they need, and companies get information to help develop new medicines and understand how their medicines are being used in the community.

Any reporting system of these activities must have a solid foundation, so that the information presented is accurate, timely and relevant. In our view, the recommendations of the Transparency Working Group have only partly met this test. Important considerations around the ability of companies to gather data, for healthcare professionals to verify it, and for data management systems to reliably report it, are not adequately addressed. Left unaddressed, the community's ability to rely on such data is undermined. Our submission therefore outlines in considerable detail the very real implementation issues raised by some of the recommendations of the Transparency Working Group, and proposes a practical and achievable solution.

We do not believe the community's interests are well served by the implementation of a system which lacks reliability and is not inclusive. The industry has made considerable progress in increasing the transparency of our activities and we would be concerned if additional changes undermined this progress.

1. Increasing transparency provisions into a voluntary code of conduct

We recognise that transparency and the trust it cultivates is essential to the development and delivery of healthcare. Transparency is a cornerstone in fostering trust between government, industry, healthcare professionals and patients. Pfizer supports the incorporation of increased transparency measures into the MA Code of Conduct where these serve to add value and further contribute to fostering trust.

In our Submission to the Code Review in 2011, and again in this submission, Pfizer proposes that Industry moves to increased public reporting of the relationships between industry and healthcare professionals.

We believe that industry and healthcare professionals must work together to ensure that any system introduced to report these transactions is accurate and effective, while not being unduly onerous on any party. We must also be considerate of healthcare professional's personal privacy and how their information will be used. Any disclosure of personal information will need to comply with the *Privacy Amendment (Enhancing Privacy Protection) Act 2012* (Cth) [1] which comes into effect on 12 March 2014. It would be damaging to implement new transparency measures without garnering the views, and support of all parties affected, as well as giving due consideration to the practicalities of this disclosure.

It is also vital to ensure that the provisions of a voluntary code such as the MA Code are workable. The ACCC's Guidance for developing effective voluntary industries codes of practice[2] notes:

> *Effective codes potentially deliver increased consumer protection and reduced regulatory burdens for business. To achieve this they must be well designed, effectively implemented and properly enforced. In contrast ineffective codes may place compliance burdens on business without any realisable benefits and potentially making signatories to it less competitive.*

Companies may decide to desist from some activities if the requirements of our voluntary code become too onerous. Pfizer contends that valid activities, notwithstanding that external critics may not endorse them, should not be rendered impractical by the imposition of complex and costly compliance requirements in the Code. Pfizer equally recognises that stakeholder views and community standards must be reflected in the Code and believes that activities must be evaluated on an ongoing basis. Activities that are no longer considered to be valid activities, after full and careful consideration, should be removed from the Code.

Pfizer considers that the purpose example provided in the ACCC's Guidance for developing effective voluntary industries codes of practice is applicable to the current Review. Pfizer proposes that it be adopted by the Code Review panel as the purpose for the Review of the Medicines Australia Code of Code 17th Edition ie to ***retain the integrity of the code, meet consumer and business expectations and keep compliance costs to a minimum while maximising the benefits that flow from effective industry codes*** [1]***.***

2. Responding to the ACCC Determination for the authorisation of the 17th Edition of the Code

Pfizer agrees with the advice contained in the ACCC Final Determination, December 2012:

> *The ACCC expects Medicines Australia to complete the work it has already commenced on increasing the level of transparency provided by the Code and to incorporate new provisions into the next edition of the Code that will facilitate greater disclosure around sponsorship and fees paid to individual doctors.*

During the ACCC consideration of its endorsement of the 17th Edition of the Code, Dr Harvey submitted that companies *would need only to include a clause in new contracts with healthcare*

professionals stating that the data collected will be published and that the ACCC should grant authorisation for one year. This points to a call for payments made by companies to healthcare professionals **that are conducted under a contract** to be reported on a named basis sooner rather than later. The ACCC clearly considered this and granted authorisation for two years rather than the five years sought by Medicines Australia noting that Medicines Australia should *incorporate new provisions into the Code in respect of individual disclosure prior to lodging any subsequent application for reauthorisation.*

3. Healthcare professional consent for payment disclosure

In the absence of Legal advice to the contrary, Pfizer assumes that any publically disclosed information provided regarding payments or transfers of value made to healthcare professionals will need to be covered by an agreed contract (signed by both the Company and the healthcare professional) in consideration of Privacy requirements and any potential litigation.

Privacy Amendment (Enhancing Privacy Protection) Act 2012 (Cth) [1] contains thirteen Australian Privacy Principles, all of which will need to be considered. The following Australian Privacy Principles warrant particular attention:

- Australian Privacy Principle 6 — use or disclosure of personal information
- Australian Privacy Principle 9 — adoption, use or disclosure of government related identifiers (unless exempted or permitted under the Act an *organisation must not adopt a government related identifier of an individual as its own identifier of the individual)*
- Australian Privacy Principle 10 — quality of personal information (includes that any personal information that is disclosed must be *accurate, up-to-date, complete and relevant)*
- Australian Privacy Principle 11 — security of personal information
- Australian Privacy Principle 12 — access to personal information
- Australian Privacy Principle 13 — correction of personal information. Of note, Principle 12 and 13 include that organisations must provide access to, and correction of, personal information, *within a reasonable period after the request is made*

To ensure that the requirements of the Privacy Legislation and other legislation are fully considered, the Code Review panel should seek Legal advice on the implications of all legislation on named disclosure and on the appropriate wording to be included in contracts. Further, advice should be sought as to whether the changes in Privacy legislation will have any impact upon the current Health Consumer Organisations disclosures. This should include advice from the Privacy Commissioner.

The Code Review panel should also ensure that the relevant professional organisations provide input on the legal implications for their members of individual healthcare professional disclosure and their capacity to support their members through these changes.

4. Overview of Pfizer's consideration of the output of the Transparency Working Group

Pfizer notes the limitations of the Transparency Working Group output. As reported on the Medicines Australia website *The Transparency Working Group members did not reach a consensus*

on every aspect of the model. It has not been endorsed or agreed upon by any of the Transparency Working Group members' organisations. The model provides a basis for consultation and feedback as part of the Medicines Australia Code of Conduct Review. This demonstrates some of the complexity of the issue and processes involved in implementing such a program.

The Transparency Working Group did not have the benefit of considering the European Federation of Pharmaceutical Industries and Associations (EFPIA) transparency model adopted 24 June 2013 which occurred after the Transparency Working Group had finalised its output. However, the Transparency Working Group did consider the US Physician Payments Sunshine Provision of the Affordable Care Act (US Sunshine Act) and appears to have been strongly influenced by it.

Pfizer notes that the legislative approach taken in the US has been long and involved, beginning in 2007 with the proposal by Senator Grassley of the Physician Payments Sunshine Act and reaching the stage of first data collection **6 years later** on 01 August 2013. The implementation is not yet complete with the Centers for Medicare and Mediaid (CMS) within the US Department of Health and Human Services stating in the Final Rule[3] that they will provide more information and guidance on the reporting requirements and timing of data review and correction.

Publically reporting the names of healthcare professional who have received transfers of value from the Medicines Australia member companies is a very serious undertaking and must proceed with certainty regarding the process, with due regard to the impact for all stakeholders and full consideration of the legal implications and practicality of implementation.

The Transparency Model put forward to report all transfers of value above a certain dollar threshold is extremely complex and is not achievable in the time frame allowed (see Operational Impact below). Reporting of all transfers of value, other than those noted as exceptions, requires considerable effort in defining the exceptions. It would require every single interaction between Industry and healthcare professionals to be identified and a determination made as to whether the interaction constitutes a "transfer of value". It would then need to be determined if the transfer of value fell under an identified exemption, and if not, whether it should be included or excluded from the reporting requirements. Such determinations would need to be made for a wide range of activities that have not been be considered in the Transparency Model e.g. equipment loans or the provision of a registered nurse to support device training.

The iterative increases in transparency in the Code have come into effect by introducing provisions outlining what activities must be disclosed and how this disclosure is accomplished. Pfizer proposes that the Code continues in this same manner and clearly outlines what payments or transfers of value must be reported on a named basis and how this should be achieved. That is, to provide a definitive list of activities that are in scope for reporting rather than saying everything must be reported unless on the exception list. There is an 'avoidance of doubt' in this approach which will lend greater confidence and certainty around the information being reported.

Pfizer is on record as endorsing the reporting of sponsorship and fees to individual doctors and believes that the Industry should progress on this in the 18th Edition of the Code. In order to do so, the transfers of value reported will need to be clearly defined discrete transfers that the Industry can feasibly implement. Additionally, healthcare professionals would need to be comfortable with

disclosure of these transfers of value and be able to manage the validation process and all stakeholders would need to perceive a benefit in reporting them.

A detailed, considered response to the Transparency Working Group Consultation and Briefing paper (Transparency Working Group paper) is contained in Part 2 of this submission.

5. Operational Impact (from a finance perspective)

System implications

There is a misconception that if a member company's headquarters organisation has developed systems to allow transparency of healthcare professional interactions, then it is only a matter of 'lift and drop' of that system into Australia.

The fact is that it is rare for any global organisation to have all markets operating on the same systems. E.g. Pfizer US is on SAP, Pfizer Australia is on Oracle.

Therefore, the development time for proposed changes will be from a zero base, and that will be dependent on the availability of global resourcing and approval for the relevant systems.

The development and implementation costs will fall solely upon the Medicines Australia member companies. Extrapolating from the US estimates, the costs are likely to be substantial. The Centers for Medicare and Mediaid (CMS) [3] estimates the costs for Pharmaceutical Companies to collect and provide the information required under the US Sunshine Act to the CMS as being **$193 million** in the first year and **$144 million** (in 2011 US dollars) annually thereafter. These costs are considered to be conservative and do not include the costs borne by the CMS which manage all aspects of data publication. The financial imposition of the additional disclosures may serve as a disincentive for companies considering membership of Medicines Australia. Costs associated with data collection will fall upon individual member companies and the costs to implement public reporting will fall upon all member companies. Should any member companies choose to leave Medicines Australia due to the impact of the increased transparency measures, there will be fewer members to bear the shared financial costs. A decline in members would be counterproductive to the whole transparency process.

In some cases, three or four systems will have to be changed, all resourced by different global teams. e.g. ERP, Expenses, Purchasing and CRM systems.

Due to the significant investment involved, Pfizer's Head Office regrettably will not be able to approve the required development spend until the ACCC has approved the exact requirements, which can then be scoped. This is prudent business and financial management. This makes implementation on January 1 2015 impossible if the requirements are only finalised in late 2014. The time taken for implementation will depend upon many factors. It is noteworthy that the US Sunshine Act was well understood (having been first introduced as a Bill into the US Senate in 2007) with the Sunshine provisions included in the Patient Protection and Affordable Care Act of 2009. Despite the fact that the resources of the US Government is supporting the implementation, data collection has only now just commenced some **six years** after the legislation was first proposed.

Consolidated Reporting/ Unique Identifier

Our understanding is that the intention of the TWG recommendation is to create a solution whereby:

i) the consumer can search by healthcare professional, and see all transfers of benefit provided by members for the reporting period

ii) Healthcare professionals can securely review and dispute their allocated transactions with all member companies.

iii) Transparency reports can be published.

For that to be possible the following should occur:

a) The ACCC has to approve the Code Review Panels' recommendations. Nothing can start at any level until the individual companies are clear about what is required of them.

b) A consolidation platform or central repository needs to be scoped, designed and built which provides uniform fields for data collection and firm direction on the unique identifier required for each healthcare professional. This identifier is essential to ensure the accuracy of information and to provide individual healthcare professionals with the capacity to verify information relating to them. At this stage there is no insight as to what that unique identifier will be and how it will be retrieved in a format that can be uploaded into a myriad of global and local systems. Further, a regular update methodology and timing has to also be found and agreed. This may involve a yet to be agreed 3rd Party (Medicines Australia, AHPRA, Independent foundation, etc.) organisation, which would then work with individual companies.

c) Once the method and source of obtaining unique identifiers has been settled, and reporting fields identified, Pfizer will be in a position to take the user requirements specifications (URS) and commence work on our requirements.

d) Pfizer will need a minimum of six months post receipt of the URS to complete the basic manual reporting of high value transfers. If a de minimus of $25 or less is approved to capture low value, high volume transfers, the required timeframe for system readiness will be, conservatively, eighteen months to two years following the development of the URS. This timeframe is based on our best efforts assessment of the likely level of effort involved to produce reports on individual healthcare professionals.

HCP Consent / Privacy/ Taxation advice

Pfizer is concerned that we will be caught in an expensive and bureaucratic process obtaining, tracking and retaining healthcare professional consents for various interactions.

However we also are concerned that a general 'opt out' provision for all interactions by a healthcare professional, due to privacy or other concerns, may result in healthcare professionals missing important educational opportunities and product information. Ultimately, patient care is at risk. As noted above, such engagement with healthcare professionals is permitted under the Code and we would be concerned if onerous reporting provisions undermined this activity.

If a healthcare professional chooses to opt in or out by event, there is a burden on the systems and administrative resources of the company to track and retain those directions.

Our recommendation is that the Code Review Panel addresses the privacy issues formally in this project. It appears guidance has not yet been sought on this despite widespread concern.

Pfizer would advise that Section 3.8 of the Transparency Working Group paper be reviewed from an Australian Tax Office perspective. The current intent and wording is not optimal from a Tax perspective.

1. Dispute Resolution

The dispute resolution process will be onerous. Under Australian Privacy Principle 13, individuals will have the right to ask what personal information a company holds on them and to request that any erroneous information is corrected. In light of this, dispute resolution would not be able to be quarantined to a 45 day period. Companies would need to resource-up to be able to respond to queries from healthcare professionals regarding the data held and requests for data correction at any time, and on any number of occasions throughout the year.

Pfizer believes there will be a need to employ additional resources to not only manage the dispute resolution process, but to manage all of the reporting.
This financial burden appears inequitable when not all companies in the industry are bound by the proposed rules within the voluntary Code.

2. Summary of timing issues and recommended next steps

The Transparency Working Group recommendations, as they stand, cannot be delivered within the timelines proposed. This is a commercial reality.

Pfizer is proposing a variation below to the types of value transfers reported, however if the Transparency Working Group requirements were approved by the ACCC as they stand, there would need to be:

a) Acknowledgement that the proposed reporting requirements will take between 18 months and two years for member companies to implement from the date of ACCC approval and

b) Acceleration by Medicines Australia of the draft Code submission to maximise the period between approval and implementation

6. Pfizer's proposals for transfers of value that should be reported on a named basis

Pfizer proposes reporting the key payments and transfers of value described in the Code under:

- Section 9.4 Company Educational Events Held in Australia,
- Section 9.7 Sponsorship of Healthcare Professionals to Attend Educational Events (Australasian and international);
- Section 9.8 Consulting Arrangements with Healthcare Professionals; and
- Section 9.9 Advisory Boards

The key payments and transfers of value (to named healthcare professionals) to report would be:

- Payments for Speaking, Steering Committees, Consultancies and Advisory boards
- Payments made for air travel in association with any of these activities
- Payments made for Registration fees for an Educational Event
- Payments made for accommodation associated with any of these activities.

These payments could be reported to Medicines Australia by individual companies in a spreadsheet for posting on Medicines Australia website until such time as more sophisticated, user friendly technology can be developed.

Pfizer also proposes the reporting of transfers of value described in the Code under:

- Section 9.11 Company Supported Medical Practice Activities
- Section 9.12 Grants and Financial Support

These transfers of value are not made to individual healthcare professionals and would be reported in a manner consistent with the reporting of Health Consumer Organisations.

The reporting proposed by Pfizer above would require significant resources, however it is achievable in the timeframe being proposed.

Pfizer notes the importance of the support that the Industry provides to the education of Australian healthcare professionals. We recognise the importance for remote and rural doctors to be able to participate in the educational events and for Australian healthcare professionals to participate in the major Scientific Meetings held overseas. This support would be more important should there be in the future a limitation on annual tax deductions for self-education such as the recently proposed limit of $2,000.

The transfers of value proposed for reporting are those with the highest costs and therefore those that healthcare professionals and consumers may consider as having the highest potential to influence. These activities are discrete and are conducted under contract agreements or could be managed in this manner with some increased documentation and resourcing. Healthcare professionals can enter into these contracts voluntarily. For implementation, agreement to the reporting of the payments as outlined in the revised Code would be incorporated into a contract, and formal agreement to the contract will need to be obtained from the healthcare professional.

Pfizer proposes that the current reporting requirements of the Code for Advisory Boards, Speaker and Steering Committee fees, Consultancy fees and the Educational Events should be removed from the Code. The reporting of high value payments and transfers of value made to individual healthcare

professionals provides significantly greater disclosure than these existing measures and to continue these reports would result in double reporting.

7. Pfizer's rationale for transfers of value to described in the Code to be excluded from reporting

Of all the transfers of value allowable under the Code and specified in Section 9 of the Code, the proposal by Pfizer is to exclude at this time the reporting of payments made for pads and pens, meals and beverages and parking and, transfers or cab charges provided in accordance with the Code. In addition to the reasons outlined below, reporting these high volume low payments would substantially delay the implementation of increased transparency measures.

The Pharmaceutical Industry has a right and responsibility under the Code to provide information about their products in an appropriate manner to healthcare professionals and to provide ongoing education to healthcare professions. The hospitality provided must be appropriate to the educational offering, where very modest hospitality is appropriate for Company Representative Details and Inservices and more substantial hospitality appropriate for extended educational meetings.

There are clear benefits to the provision of hospitality in association with an educational event. At the most modest level it allows a healthcare professional to engage in an educational activity during a meal break. The same is true for meetings held out of hours at venues such as Universities or hospitals.

The current provisions of the Code comprehensively cover the requirements for hospitality:

- Section 9.4.3 includes that meals and beverages provided at company educational events held in Australia must *be secondary to the educational* content and appropriate for the educational content and duration of the meeting and should *not be excessive*.
- Section 9.5.5 requires that Companies must *critically examine whether any hospitality provided at the sponsored educational event is appropriate for the educational content and duration of the meeting and is secondary to the educational content*
- Section 9.7.7 requires that meals or beverages offered by companies to sponsored healthcare professionals *must be secondary to the educational content*, must be *appropriate for the educational* content and duration of the meeting and must not be excessive.

The Code also prohibits the subsidising or paying of hospitality, travel or other expenses of any guest, family, companion or any other person associated with a healthcare professional under any circumstance.

Pfizer does not support at this time the reporting of parking fees, airport transfers and cab charges where these transfers of value are allowable under the Code. These transfers of value are of a lower value than those proposed for reporting by Pfizer. They are additionally less able to be precisely predicted (due to unexpected wait times or events running overtime) and therefore not able to be accurately determined at the time of the contract agreement.

Given that any hospitality is modest and secondary in nature to the educational content of any meeting Pfizer does not support the reporting of meals and beverages on a named basis at this time. Again these transfers are of a lower value than those proposed for reporting by Pfizer and are less able to be precisely predicted at the time of the contract agreement (the cost of the meals and beverages in many cases is not set, and will only be established after the event)

The reporting of transfers of value of this low order is not included in any voluntary Industry Code. The implementation of reporting to this level would be a substantial undertaking, is not consistent with the principles of what constitutes an effective voluntary industries code of practice, goes far beyond the expectations inferred by the ACCC determination and is not feasible in the time frame allowed. Further detail is provided above under "System Implications".

Clearly when the Code is changed in any manner, the magnitude of the change must be proportional to the benefits the changes will provide. Additionally the lead time must be sufficient to allow for Member Companies to make all the necessary changes to both comply with the Code, to have fully considered all the ramifications of the changes and for all stakeholders to become engaged in dialogue and to be able to input to the changes. At the present time there are a number of unknowns regarding costs, stakeholder support, methodology and legal implications for reporting individual payments. Additionally, the timeframe does not allow for a consensus position to be reached. Committing to a course of action without a real certainty on how it can be achieved would not be responsible.

With the clear objective of providing the most meaningful increase in transparency in a timely manner, and in recognition of the significant and numerous concerns and practical limitations in place, Pfizer proposes that the enhanced transparency requirements should be restricted to the reporting on a named basis, only those payments and transfers of high value.

8. Consideration of the provisions of the US Physician Payments Sunshine Provision of the Affordable Care Act (US Sunshine Act)

As noted earlier the legislative approach taken in the US has been long and involved , beginning in 2007 with the proposal by Senator Grassley of the Physician Payments Sunshine Act and reaching the stage of first data collection **6 years later** on 01 August 2013. The implementation is not yet complete with the Centers for Medicare and Mediaid Services (CMS) within the US Department of Health and Human Services stating in the Final Rule that it will provide more information and guidance on the reporting requirements and timing of data review and correction.

The Sunshine Act timeline:

2007 Senator Grassley proposes the Physician Payments Sunshine Act of 2007.

2009 The Physician Payment Sunshine provisions were included in the Patient Protection and Affordable Care Act of 2009

March **2010** The Patient Protection and Affordable Care Act of 2009 was signed into law

Dec **2011** Centers for Medicare and Mediaid (CMS) within the US Department of Health and Human Services sought public comment

February **2013** The Final Rule implementing the Sunshine Act is released containing 35 pages of regulations and 251 pages of commentary and explanations

Aug 1 **2013** Data capture begins

Sept 30 **2014** Data publically available.

External stakeholders have recommended that the provisions of the US Sunshine Act be incorporated into the Medicines Australia Code. Pfizer accepts that to meet consumer expectations, all models of transparency, those imposed by legislation or applied under voluntary Codes, need to be considered. There are however important distinctions to be made concerning the US Sunshine Act:

- The US Sunshine Act applies universally to all manufacturers of therapeutic goods and devices. The provisions of the Code pertaining to relationships with healthcare professionals are applicable to MA Members only and do not apply across the healthcare sector. Unreasonable compliance burdens under the Code would introduce competitive disadvantages for Member Companies.
- The US Sunshine Act provides a legislated requirement to report specified personal details of healthcare professionals, Privacy legislation is not breached when information is provided appropriately for a legislated purpose. Such exemptions do not apply in Australia for voluntary Codes of Conduct therefore Privacy Legislation requirements will need to be fully considered to ensure that they are not breached.
- The provisions of the Code pertaining to relationships with healthcare professionals apply to all those who may prescribe, recommend or supply a prescription medicine whilst the US Sunshine Act applies **only** to prescribers.
- Following the passage of the legislation in 2010, the US government through the CMS has funded the development of the implementation strategy which included consideration of the extensive Industry and public submitted comment. The costs of developing the technology to support the reporting of these costs into the future are born by the US government. Additionally the CMS will be supporting physicians using the technology and has developed tools to assist physicians track transfers of value from the Industry. In Australia, the entire work and costs of additional transparency requirements under the Code would need to be borne by Medicines Australia Member Companies.
- The US Pharmaceutical Industry operational environment is different to that of Australia. Direct to Consumer Advertising is permitted in the US. It could be the case that the scope of transparency imposed by the US Sunshine Act has taken this into consideration (ie with promotion right down to the consumer level, healthcare professionals and consumers desire transparency of even low value interactions).
- Publication on payments to healthcare professionals under the US Sunshine Act will not occur until 2014. There are no data available to gauge what benefits the Sunshine Act will deliver and whether there will be any unintended consequences. It could be that consumers

actually want more up to date information directly from their healthcare professional during a consultation when a decision to prescribe a prescription medicine is made. Pham-Kanter et al [4]have looked at the effect that the implementation of Sunshine Act legislation in two States in the US had on the rates of prescribing of branded versus generic products for HMG–Coenzyme A reductase inhibitors (statins) and selective serotonin reuptake inhibitors (SSRIs). They found that "*Overall, there were negligible to small effects of the disclosure laws in Maine and West Virginia for both statins and SSRI."* The authors commented that "*Overall, our results suggest that the Physician Payments Sunshine Provision in the federal health care law may have a limited effect on prescribing and on expenditures."*

Part 2

Response to the Transparency Model Consultation and Discussion Paper

This response is aligned with the Pfizer position on transparency outlined in the previous section and should be read in the context of this position.

Glossary

Pfizer proposes the reporting of clearly specified high value payments or transfers of value to healthcare professionals on a named basis. The details of the reporting requirements should be included in the relevant subsections of Section 9 of the Code or alternatively, as is the case with the current Guidelines, covered under a separate section of the Code.

Pfizer proposes the reporting of payments **inclusive** of GST for the following reasons:

- Verification by the HCP will be assisted with the amount paid being the amount reported.
- Removing the GST from payments is an additional financial manipulation of the data and would require system changes should the rate of GST change.
- Reporting of costs paid in Australia exclusive of GST accurately represents the cost to the company as GST can be claimed back, however reporting of meals and accommodation associated with an international meeting minus tax is not an accurate reflection of cost to the company as the overseas tax cannot be claimed back.

1. **General Requirements and**
2. **Limitations**

Timeframe for disclosure

Consideration of reporting timelines should take note of the experience with the Educational Event Report timing. Data collection periods ending 31 December produce logistical problems for report preparation due to January being the principle holiday period in Australia and the period in which companies focus on Representatives training. The Code was revised in response to these practical considerations to move the reporting period out three months. Additionally, the timing for healthcare professional validation as proposed in the paper will in many years be impacted by the Easter holiday period.

The Code Review process will culminate in the 18th Edition of the Code of Conduct being submitted for authorisation by the ACCC in the middle of 2014. Until the Code has endorsement by the ACCC Medicines Australia Member Companies will not have certainty as to what the changes to reporting requirements will be. Companies will not be in a position to invest in developing the necessary data capture processes and systems to comply with increased transparency measures until the exact requirements are known. It is clear that reporting will need to be:

- Completely accurate, to facilitate all aspects of reporting and to comply with Privacy Legislation. Australian Privacy Principle 10 requires the data to be *accurate, up-to-date, complete and relevant*. Inaccurate data will result in considerable inconvenience to healthcare professionals who will need to expend considerable time and effort in correcting any inaccuracies. Inaccurate data could become publically available if there is a delay in determining the correct data. This would be indicated in the report but could be an unfair burden for healthcare professionals called upon by consumers to explain disputed data. The Code Review panel should seek Legal advice as to whether published disputed data resolved in the favour of the healthcare professional could place a company at risk of any litigation. Inaccurate data not identified and corrected would constitute a breach of the Code.
- Capable of allowing individual HCPs to access data to be reported against their name whilst ensuring that data on other HCPs is not accessible until the time of public reporting.
- Will not be achievable in the timeframe set out by the Transparency Working Group paper. The extent of the likely delay of implementation is dependent upon what payments are within scope for reporting. Pfizer proposes a move to reporting high value payments at this time. For this proposed scope of reporting, following the determination of the ACCC by December 2014, collection of data could commence on 01 July 2015. The six month intervening delay is required to bring into effect the processes and systems required for this reporting. In the absence of a sophisticated technological solution developed by an as yet unidentified third party, initial reporting should be in the form of a spreadsheet from each member company which would be posted individually on the Medicines Australia website.

Impact on current reporting requirements

The Educational Event, Advisory Board and Consultancy Reports should be discontinued at the time individual HCP data collection is commenced, i.e. discontinue Educational Event, Advisory Board and Consultancy Reports as of 30 June 2015.

3. Information to be reported

The use of the Australian Health Practitioner Regulation Agency (AHPRA) number as the unique identifier may not be considered appropriate by healthcare professionals as this could be taken as linking disclosure to their professional registration. As noted earlier, under Transparency in Part 1 of this submission, a source for AHPRA numbers or other unique identifiers, in a format that can be uploaded into the financial systems used by Pfizer (with regular updates to maintain currency), needs to be identified and, importantly, Australian Privacy Principle 9 needs to be taken into consideration.

Clearer guidance is needed on the details of the healthcare professional that require reporting. Healthcare professionals may have more than one AHPRA number and more than one business address. The Transparency Working Group paper states that the locality of the primary business of the healthcare professional recipient must include City, State and Postcode. This is at slight variance to details in APHRA which are Suburb, State and Postcode.

If Privacy legislation, practical impediments and healthcare professional concerns result in the AHPRA number not being used, there must be careful consideration of what healthcare professional

details will need to be disclosed in order to correctly, uniquely and accurately identify the individual healthcare professional. For the purposes of the reporting proposed by Pfizer the following details are suggested:

- Full name (as listed on AHPRA Registry)
- Health profession
- Name of principal place of practice
- Address of principal place of practice

For reporting purposes, the date of payment should be the date that the event occurred for payments associated with Educational Meetings, Advisory Boards and other activities that occurred at a discrete point in time. Clear guidance should be provided for other payments that occurred over a period of time and payments shared by a number of member companies.

Pfizer has proposed a definitive list of payments for reporting. The category of payment should be consistent with the Code and the subsection of Section 9 of the Code that the payment relates to. The current hierarchy of payments in the Guidelines could be further developed to provide guidance.

The implications of Privacy, Taxation (including Fringe Benefits Taxation) and other legislation for the reporting of individual payments and transfers of value to healthcare professionals needs to be fully determined before data collection can commence.

Pfizer is not proposing the reporting of a Royalty or licence fee. Nevertheless, we note that this would not be appropriate as such payments are covered by Confidentiality Agreements, and the Code would not apply as these agreements as they are usually entered into at the global, rather than the affiliate, level.

4. Payments for CPD programs

Pfizer proposes the reporting of payments made for Speakers, Steering Committees, air travel, registration and accommodation for **all** educational events.

5. Exclusions

The exclusions list includes activities that are not in the scope of the Code, e.g. business to business trading agreements. For clarity and certainty, a definitive well proscribed list of reportable payments related to activities included within the scope of the Code should be determined. The alternate approach suggested in the Transparency Working Group paper will require every single interaction between Industry and healthcare professionals to be identified and a determination made as to whether it constitutes a 'transfer of value", and if so whether it should be included or excluded from the reporting requirements. Such determinations would need to be made for a wide range of activities e.g. equipment loans and the provision of a registered nurse to support device training.

Clear guidance will also be required to cover circumstances when payment, such as speaker or consultancy payment, is made to a healthcare professional's company rather than to the individual healthcare professional.

The reported payments should be the accurate figure for the payment that has been made. There should be no apportioning of other costs into the figure reported. Apportioning would complicate the data collection and data verification processes unnecessarily.

6. Procedures for electronic submission of reports and
7. Process

It is not possible to implement electronic submission of reports without the user requirements specifications.

The following elements of the proposed Transparency Model are yet to be developed:

- What unique identifier will be used and who will provide this to companies in a format that is able to be uploaded and updated in financial systems
- A third party to host the electronic repository in a publically accessible site (and the URS for this application)
- A method for providing healthcare professionals with access to data for validation purposes
- The Dispute Resolution process
- Measures required to address Privacy, Taxation and other Legislated requirements

Australian Privacy Principles 11 and 12 describe the rights of an individual to access their personal information held by a third party, and request correction of any incorrect data, *within a reasonable period after the request is made.* These principles would be expected to override any restrictions on doing so included in the Code. In this case, individual data corrections would be required to be made at any time upon request. The Code Review Panel should seek further advice on this.

8. Penalties

Further clarity is required regarding Penalties:

- If a single figure is inaccurate, is this a single breach or is it multiplied by the number of times it was reported? For example, if there was an error in reporting accommodation cost and there were 20 attendees provided with accommodation, would this be 1 or 20 breaches.
- What is an **intentional** failure?
- Why is **any** late reporting automatically regarded as a **severe breach**?

Part 3

Pfizer proposals for changes to Medicines Australia Code of Conduct 17th Edition in addition to transparency changes.

Code Section 1.4 Unapproved Products and Indications

The Medical community is proficient users of electronic resources and increasingly sources information regarding pharmaceutical products on line. In response to this, companies develop websites and mobile applications directed to healthcare professionals to provide information about treatments. Several companies have developed Medical Information sites which allow healthcare professionals to search for Medical Information responses for information they are seeking. The search results are tied to the search terms entered by the healthcare professional.

Pfizer proposes that the Code be amended to include a statement that information on unapproved products or indications may be included in the responses contained within a Medical Information website where these responses are only available after the healthcare professional has entered relevant search terms for the response. Pfizer considers that this is analogous to a healthcare professional calling or emailing Medical Information, i.e. the information is being provided on an unsolicited basis. Appropriate disclaimers in the response documents (as with all Medical Information responses) will clearly identify any information that is for unapproved products or indications and that the provision of this information is not intended to advocate any use not covered in the product prescribing information. Suggested wording follows below in bold.

Company personnel from the medical department, including field based medical personnel, may provide information on unapproved products or subjects not covered by the Product Information, such as unapproved indications, to healthcare professionals upon receipt of an unsolicited request. **Companies may make such information available in company Medical Information websites and mobile applications provided that these responses are only accessible after the healthcare professional has entered relevant search terms for the response, that is the information is only available on an unsolicited basis.** *The information provided must be selected and/or prepared by the medical department and any resulting dialogue about an unapproved product or indication with the healthcare professional should be with medical department personnel and not a member of a commercial function or team.*

Code Section 3.3 Change of Clinical Significance and the addition of a Boxed Warning

Background

The requirement to communicate changes of clinical significance related to product safety to healthcare professionals is a Code requirement only. It is not a legislative requirement, nor is it a provision in other Codes internationally. Further it is a requirement that applies to promoted products only. Black box warnings are used internationally to highlight safety concerns and are required on a permanent basis unless information comes to light that reduces the safety concern.

Pfizer believes that the current methods for communicating changes of clinical significance are flawed and not necessary. Pfizer proposes that boxed warnings should be given greater prominence in promotional materials.

Change for the 'addition of a Boxed Warning'.

Pfizer proposes that Section 2.0 should be amended to require that all promotional material must include any box warning (in ≥2mm font outlined in a box). This would communicate this significant safety information clearly to healthcare professionals on a permanent basis. This would also require the removal of the boxed warning requirement from the **Minimum Product Information-Section 3.2 f)** as this requirement would then be superfluous.

Change for 'Clinical Significance' communication

There are three options for the communication of changes of clinical significance in the Code, each of which have issues.

- Highlight the changes in all representations of the Product Information **for inclusion with promotional material to healthcare professionals** for 12 months from the date of the change (issues detailed below)
- Provide a prominent statement on Product websites. Not all promoted products have a website. If the Corporate website Product Information page is used for this purpose, highlighting the changes of clinical significance may have the effect of promoting to the public (e.g. by citing a new approved indication)
- Send a Dear Healthcare Professional letter. This is a onetime activity that may not be remembered when the healthcare professional is reviewing promotional material. There are also considerable costs associated with this method of communication.

Product Information provided in association with promotional materials.

The provisions of the Code ensure that relevant Product Information is available to healthcare professionals. These Code requirements ensure that healthcare professionals are able to access **all** relevant information before a decision concerning a product is made.

As noted in the Guidelines, *The overall purpose of the Minimum Product Information is to provide sufficient, relevant information to a healthcare professional in the context of viewing promotional material and advertisements. Healthcare professionals should have access to clinically relevant*

information when they are prescribing a product. The Minimum Product Information is a succinct précis of the Product Information. It is not intended to replace the full Product Information, which all prescribers and other healthcare professionals should be familiar with, or familiarise themselves with, before prescribing, recommending or administering a prescription product.

The Minimum Product Information contains succinct statements on the approved indication(s), the contraindications, clinically significant precautions, clinically significant interactions, very common and common adverse effects, and the dosage and method of use (and currently the full text of the box warning). All of this information is important however the Product Information is a complex document which healthcare professionals should refer to in full. Healthcare professionals have ready access to electronic versions of Product Information which they can easily search for all information or locate specific information relevant to the clinical setting.

The proposed requirement that any boxed warning must appear in all promotional material would highlight box warnings to healthcare professionals far better and more persistently than adding an asterisk for 12 months.

Issues with highlighting changes of clinical significance in Product Information for 12 months from the date of change.

In light of the issues with providing statements on Product websites and sending Dear Doctor Letters, many companies continue to meet the Code requirements by highlighting the changes in all representations of the Product Information.

Asterisks in Minimum Product Information and full Product Information.

Pfizer has some significant concerns around the *changes of clinical significance* requirements.

1. *Changes of clinical significance relating to product safety are likely to influence the decision to prescribe*. The current product safety information is summarised in the Minimum Product Information. More recent safety information is no more important than longstanding safety information.
2. The 12 month period for inclusion is arbitrary and requires tracking, which can become complex if changes occur more than once within a 12 month period
3. The asterisking changes of clinical significance within the body of the full Product Information is of dubious benefit given that the asterisks can become lost in the volume of the text . Reference Manual Advertising allows for advertisements to reference where the Product Information is located within the reference manual. Highlighted changes of clinical significance when **included** by sponsors in Product Information documents **are not carried forward into the Australian Prescription Product Guide, MIMS bimonthly or MIMS Annual.** Therefore referencing to Product Information in a Manual does not allow for highlighting of changes of clinical significance.
4. It is open to interpretation whether the removal of an asterisk from the full Product Information equates to an editorial change requiring notification to the TGA. If notification to TGA as an editorial change is interpreted as being required, there are resource and cost implications associated with the removal of asterisks after 12 months. Companies may leave them in the Product Information until another change is required.

5. The Code requirements ensure that prescribers are reminded to *refer to the **full** product information before prescribing*. It is not realistic to believe that healthcare professionals retain a detailed knowledge of all the clinically significant information contained in the Product Information. Highlighting recent changes may be inadvertently misleading as healthcare professionals may interpret this to mean that the changes are of the special importance when in fact more recent changes are not necessarily more important than longstanding information.
6. If a Product Information undergoes a Category 1 change, a new document is approved. There is no specification as to what should be done in this case-asterisk the newly included information or treat the document as a clean new version with no changes asterisked. Both approaches have been seen to be applied.
7. The *change of clinical significance* requirement only applies to Product Information included with Promotional Material and therefore only for promoted products. This causes issues when a normally non-promoted product is promoted on a 'one off' occasion to healthcare professionals.
8. As already noted, highlighted changes of clinical significance when **included** by sponsors in PI documents **are not carried forward into MIMS bimonthly or MIMS Annual.** This means the current practice of highlighting changes of clinical significance is very limited in its application, has not been adopted by reference manuals and is not something that healthcare professionals are consistently exposed to or understand.
9. There is wide variation in how the asterisk is placed by different companies. It may appear immediately before a word, or a sentence, or a paragraph or immediately after a word, sentence or paragraph.

Given all of the above, it would appear that highlighting changes of clinical significance for twelve months is a well intended provision of the Code that is not likely to be delivering the intended benefit.

Pfizer proposes that Section 3.3 should be removed and Section 2.0 revised to include the requirement that all promotional materials must include the box warning.

Multiple Code Sections –Font sizes

Pfizer believes that the current font size requirements are unnecessarily complex and are already being set aside for electronic media.

The preceding suggested change would remove font size requirements for *Please note changes in Product Information* (3mm). The currently specified font sizes are 1mm, 1.5mm, 2mm and 3mm.

Pfizer recognises that it is important to include a minimum font size for core information and the Minimum Product Information. Additionally, it is important to give appropriate prominence to certain text in promotional materials. However it is not apparent why the text outlining the PBS listing has a smaller minimum font size to other statements.

Pfizer's proposal is to have the same font size for PBS box text and for other text currently required to be in ≥3mm font.

2mm minimum font would be the required text size for any text requiring prominence.
Text requiring prominence would be:

- Text in boxed warning
- Text in PBS box
- All qualifications for claims
- "*Refer to Product Information before prescribing*;"
- Statement to the effect that further Information is available on request from the supplier
- "*Not statistically significant"*
- Statements required to accompany claims based on animal or laboratory data
- Identification that an article is company commissioned
- Reference to location of the Primary advertisement or the PI index or advertiser's index.

Additional requirements for electronic media
The current guideline for text contained on electronic devices used for detailing is:
Text font, size and colour must be considered to ensure legibility. The resolution provided by different screen sizes should also be taken into account when accessing legibility. All text must be easily visible from a comfortable viewing distance prior to zooming or utilising other similar functions.

Pfizer proposes that there should be further guidance provided to specify that text requiring prominence in printed media (text requiring a minimum font size of 2mm in this submission) should be given prominence in electronic media.

Code Section 7 Starter Packs

Pfizer does not propose any changes to the provision of starter packs. The provision of starter packs allows healthcare professionals the opportunity to initiate treatment and to evaluate the response without delay and without cost to the consumer. For prescription products that are also medical devices, the provision of starter packs allows the healthcare professional to demonstrate the use of the product (inhaler, injection, spray etc) to the consumer.

Patient adherence is a well recognised, longstanding problem. The first step to adherence is to start treatment and consumers are more likely to start treatment if they leave their doctor's office with the medicine they need. Consumers are also likely to be more receptive to being trialled on a number of medicines to determine tolerability if they have not had to purchase each medicine.

The Code requirement that the starter pack should be 1/3 the size of the Trade Pack is unique and appropriate for initiation of treatment. Pfizer however does not believe that Starter Packs should be used for Product Familiarisation Programs (see below).

Code Section 8 Product Familiarisation Programs

The code requires the use of Starter Packs and prohibits the use of Trade Packs for Product Familiarisation Programs.

As noted above, Starter Packs are appropriate for healthcare professionals to initiate treatment. The 1/3 Trade Pack size is appropriate for this purpose.

Product Familiarisation Programs have a different rationale to the provision of Starter Packs. Product Familiarisation Programs are intended to provide healthcare professionals the opportunity to evaluate and become familiar with a **new** product or **new** therapeutic use of a product. The enrolment period for Product Familiarisation Programs can be up to six months. The duration of Product Familiarisation Programs should be determined by clinical rationale, and in recent years programs have run for much longer than originally envisaged due to extended delays in gaining a PBS listing.

For a Product Familiarisation Program that runs for six months, for a product taken once daily, a consumer would receive 4 starter packs every month and 24 starter packs over the six months. The healthcare professional must take due care to ensure the correct number of starter packs are provided and ensure adequate secure storage of the starter packs (storage capacity can be an issue as four Starter Packs take up significantly more space than one Trade Pack).

Pfizer proposes that Trade Packs should be allowed for Product Familiarisation Programs. We believe that Trade Packs are a better fit to the purpose of Product Familiarisation Programs, would be more easily managed by healthcare professionals and provide a smoother transition to PBS supply. The provision of Trade Packs would also avoid the confusion that consumers may have with a packaging change after six months or more of treatment.

Code Section 9.4.4 and 9.7.5

Pfizer proposes that it should be a requirement that travel should be for the meeting alone and via a direct route.

It is suggested that wording be added in both these Section stating that ***"travel may only be provided in direct association with the educational event, any flights provided must be by the most practical direct route to and from the educational event".***

Code Section 9.10 Reporting Payments to Healthcare Professional Consultants and Advisory Board Members and Code Section 37.4 Educational Event Reports

As outlined under "Transparency" at the beginning this submission, Pfizer proposes that the current reporting requirements of the Code for Advisory Boards, Speaker and Steering Committee fees, Consultancy fees and the Educational Events should be removed from the Code. The reporting proposed by Pfizer of high value key payments and transfers of value made to individual healthcare professionals provides significantly greater disclosure than these existing measures and to continue these reports would result in double reporting.

Code Section 12.6

Pfizer proposes that the requirement to include payments to healthcare professionals for Market research in the Consultancy report should be retired with the Consultancy Report.

Code Section 13.3 Promotion to the General Public

Pfizer suggests that there should be discussion and consideration on what constitutes "*promotion to the general public"* particularly regarding product websites. Consumers are increasingly using the internet to access health information. This has resulted in the following:

- Many country-specific barriers to information have been bypassed due to the advent of the internet.
- Consumers can access product websites of any global pharmaceutical company, simply by typing a product name into a search engine and being directed to an American site.
- In addition consumers can access a wide variety of non-industry sites potentially containing inaccurate or incorrect/dangerous information.
- Current Code restrictions on consumers accessing Australian product websites do not acknowledge this reality and do not serve to prevent consumers accessing information on prescription products on the internet.
- Permitting Australian companies to develop product websites with **balanced, accurate, substantiated information** which consumers could access would be of value in balancing against the unsubstantiated information or information based upon discredited science.

Consumers now have access to huge amounts of information regarding prescription products on the internet. Inevitably some of this information is not appropriate as it relates to indications that are not approved in Australia. Further some of this information is erroneous and not consistent with accepted medical treatment standards. The information that suppliers of these products are able to provide is strictly limited. Clearly, companies would be entirely accountable for any information provided on product websites and the content would need to be robustly defined. This is not a call for direct to consumer advertising, it is a request to consider how companies can responsibly provide information to consumers in a factual evidence based manner intended to facilitate the quality use of medicines.

Code Section 13.6 Educational Information to the General Public and Code Section 13.7 Disease Education Activities in Any Media

The difference between these two material types is not clear. Section 13.6 covers information on medical treatments and prescription treatments and Section 13.7 covers activities that provide information, promote awareness and educate the public about health, disease and their management.

It would be helpful to create a clearer distinction between these two sections. It may be clearer if the distinction is made between:

- Information provided to the general public and
- Information that is provided to members of the general public after they have been prescribed a prescription product (which may also be able to be accessed by healthcare professionals to use in discussions with consumers after the decision to prescribe has been made).

As noted above, Pfizer proposes that there should be further discussion on what information a company may provide to consumers on product websites.

Code Section 30.2.1 Review of promotional materials and activities

The proactive review conducted by the Monitoring Committee is an important component of the Code. Feedback from the Monitoring Committee furnishes opportunities for continuous improvement and the robust review undertaken provides confidence to external stakeholders that companies are compliant with the Code.

The Monitoring Committee is required to review three types of promotional material across three different therapeutic classes and three different types of conduct across all therapeutic classes. In order for the Committee to conduct these reviews, companies are now being requested to supply the references in addition to the materials. Even with the provision of references, the reviews of materials can extend over a number of meetings.

With the increased transparency measures proposed by Pfizer, the current Educational Event reporting would be discontinued which would also result in the Monitoring Committee review of the Educational Event Report being discontinued. It is envisaged that there would be Monitoring for the new transparency measures, and given the large volume of individual payments, this work undertaking will be well beyond the scope of the current review.

Pfizer proposes that the number of Monitoring Committee reviews be reduced.

The previously stated aim (Code 14th Edition) was to review materials from the 15 Therapeutic classes within a two year period. Pfizer proposes that in light of the increased burden of work to monitor the proposed individual healthcare professional disclosure and the requirement to provide both the materials and supporting documents for promotional activities reviewed, a more

reasonable aim would be for the review to cover the span of materials and activities within a three year period.

Code Section Appendix 1 Intercompany Dialogue Guidelines (p146) Change: Remove requirement for Senior Executive Officer to sign IC dialogue

The Senior Executive Officer should be able to receive the IC dialogue minutes electronically; the requirement to lodge a signed copy should be removed. Pfizer proposes the deletion of the words crossed through below.

If the Senior Executive Officer is not present at this meeting, a record of the meeting should be provided to them ~~for their signature~~. This ~~signed~~ record of the meeting must be submitted with the complaint should it proceed to Medicines Australia.

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[1] http://www.comlaw.gov.au/Details/C2012A00197

[2] Australian Competition & Consumer Commission Guidelines for developing effective voluntary industry codes of conduct July 2011 http://www.accc.gov.au/system/files/Guidelines%20for%20developing%20effective%20voluntary%20industry%20codes%20of%20conduct.pdf

[3] Final Rule (US Sunshine Act) http://www.gpo.gov/fdsys/pkg/FR-2013-02-08/pdf/2013-02572.pdf

[4] Pham-Kanter G, Alexander GC, Nair K (2012). "Effect of financial disclosure laws on physician prescribing". Archives of Internal Medicine 172: 819–821. http://archinte.jamanetwork.com/article.aspx?articleID=1170047